IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADVANCED CARDIOVASCULAR SYSTEMS, INC. and GUIDANT SALES CORPORATION, Plaintiffs, v. MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC., Defendants.	Civil Action No. 98-80 (SLR) (Consolidated with C.A. No. 98-314 (SLR) and C.A. No. 98-316 (SLR))

ACS'S POST-TRIAL BRIEF IN RESPONSE TO MEDTRONIC'S ALLEGATIONS OF INEQUITABLE CONDUCT

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September 19, 2005

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

I. INTRODUCTION

Medtronic's brief exemplifies the type of unwarranted, trumped-up allegation of inequitable conduct that the Federal Circuit has condemned as an "absolute plague" on the patent system. Medtronic's account of the events that allegedly took place at ACS in 1989-90 is largely fictional, amounting to little more than a conspiracy theory and an attempt to smear the reputations of ACS's employees and legal counsel. What little evidentiary support Medtronic has for its allegations comes primarily from Michael Boneau, a paid Medtronic consultant whose trial testimony was, to put it mildly, questionable. When confronted with blatant inconsistencies in his prior sworn testimony, Boneau flippantly blamed it on the fact that he has "more time on film than Jerry Seinfeld," a TV comedian. Yet this is no laughing matter. The reputations and livelihood of honest businesspeople and members of the bar are at stake. Despite such serious ramifications, Medtronic justifies its accusations by heaping supposition on top of speculation and asking the Court to draw inferences without any supporting evidence. It is questionable whether that approach even satisfies Rule 11, let alone the demanding standard of clear and convincing evidence needed to support a finding of inequitable conduct.

The legal merits of Medtronic's inequitable conduct arguments are equally lacking. To begin with, most of the so-called "Boneau prior art" is not prior art with respect to the Lau claims. For instance, Boneau's alleged "suture stent," which existed (if at all) only in his mind, is both uncorroborated and undocumented. Dr. Stertzer's alleged "tradition" of implanting stents "crown-to-crown" is likewise uncorroborated and therefore not prior art.

The Boneau patent application, which only became prior art under 35 U.S.C. § 102(e) when the Boneau '331 patent issued in 1994, is not material to the Lau claims because it teaches *away* from using short rings that are not in and of themselves stents and teaches *away* from connecting such rings together. Dr. Segal—an interventional cardiologist and medical-device designer—made this point absolutely clear. In rebuttal, Medtronic offered only the testimony of a sheet-metal expert (Dr. Wagoner) and a civil

engineer (Professor Saigal),[1] neither of whom is skilled in the stent art. Their unsubstantiated opinions simply do not amount to clear and convincing evidence of materiality, particularly since the Boneau patent has been cited in *fifteen* Lau patents—including three of the four patents-in-suit—and has *never* been the basis of a rejection. Moreover, the jury in the liability trial deliberated for just a few hours before finding, *inter alia*, that the Lau patents are not invalid over Boneau.

The Boneau application is also not material because it is cumulative to other references that were submitted during prosecution of the Lau patents. As just one example, Lee '917 discloses a plurality of balloon-expandable, undulating rings with a length less than their diameter ("L<D"), precisely as Medtronic alleges Boneau discloses.

Finally, Medtronic has not offered a shred of proof that ACS acted with deceptive intent, a required element of inequitable conduct. Medtronic argues, instead, that ACS bears the burden of *disproving* deceptive intent, which, of course, is flatly contrary to the law. Medtronic also asserts that deceptive intent may be inferred from the fact that ACS maintained the attorney-client privilege in this case. That, too, is improper as a matter of law. Thus, in the end, Medtronic's "proof" boils down to a cobbled-together timeline and a fictional account of events. Mere speculation, though, cannot satisfy the threshold level of intent needed to prove inequitable conduct, let alone the extremely *high* level of intent needed here, where Boneau has little or no materiality to the patents-in-suit.

II. STATEMENT OF FACTS

A. Medtronic's Inequitable Conduct Allegations Have Changed Repeatedly

Like the testimony of its key witness Mr. Boneau, Medtronic's allegations have changed constantly throughout this litigation. Initially, it took a "shotgun" approach, leveling a slew of accusations and abandoning them as each proved meritless. As the liability trial approached, however, Medtronic gave every indication that it intended to drop its inequitable conduct case altogether. For instance, it opted not to depose any of the attorneys involved in the Lau prosecution. It was not until the

[1] Dr. Saigal is referred to herein as "Professor Saigal" to avoid confusion with Dr. Segal.

pre-trial hearing on February 2, 2005, that Medtronic revealed it still intended to pursue inequitable conduct. When asked the basis for its claim, Medtronic's counsel informed the Court that it "boils down simply to the fact that Mr. Lau had the *Boneau patent application* in his hands and did not make that available to the PTO for years during the prosecution of his patent." (D.I. 580 at 26-27, emphasis added.)

At some point before the inequitable conduct trial in June 2005, Medtronic apparently realized that the Boneau patent application, by itself, could not provide a basis for inequitable conduct. For instance, Medtronic undoubtedly realized that, because it had asserted Palmaz '417 as an *anticipation* reference and Boneau '331 only as an *obviousness* reference, Boneau can be no more than cumulative to Palmaz '417 as a matter of law. Likewise, Medtronic likely realized that the Boneau patent application is cumulative to other cited references, e.g., Lee '917.

Medtronic attempted to solve this dilemma by coining a new phrase—"the Boneau prior art"—in the Supplemental Joint Pre-trial Order, filed just one month before the inequitable conduct trial in June. (D.I. 664.) According to Medtronic, "the Boneau prior art" now encompasses not only the Boneau patent application but also an amorphous hodgepodge of other information, such as the personal thoughts of Michael Boneau about the alleged "suture stent" and Dr. Stertzer's alleged "tradition," in the late 1980s, of implanting Boneau stents in a "crown-to-crown" configuration [2] (D.I. 683 at 2.) As will be explained, however, none of those concepts is prior art to the Lau patents.

B. Boneau's Initial Contact With ACS in 1989

In the spring of 1989, having been rejected by several other companies (D.I. 670 at 80, 159-60), Mr. Boneau had an initial meeting with Will Sampson at ACS to see if ACS had any interest in acquiring the Boneau stent technology. (D.I. 670 at 210-11.) At trial, Mr. Boneau testified that he showed Mr. Sampson *prototypes* of the Boneau stent and discussed various technical features during that initial

[2] The alleged "crown-to-crown" tradition was clearly an afterthought, for Medtronic never asserted it as prior art during the liability trial, never listed it as prior art on a § 282 notice, and did not even include it in the Supplemental Joint Pretrial Order filed just one month before the inequitable conduct hearing. Indeed, the first ACS heard of Medtronic's "crown-to-crown" argument was the *night before trial*, when demonstrative exhibits were exchanged. (D.I. 671 at 590.)

meeting. (D.I. 670 at 114.) Yet that testimony *flatly contradicts* Boneau's sworn deposition testimony from 1999:

> Q. Did you provide to ACS or show ACS at this meeting, after you signed a confidentiality agreement, any prototypes?
> A. Not at that time, no.
> Q. Did you later show them any prototypes?
> A. Yes.
> Q. When was that?
> A. In September, on or about late 1990.

(*Id.* at 156.) When confronted with this glaring inconsistency at trial, Boneau retorted:

> I have been—I have more time on film than Jerry Seinfeld has. I mean, I have over 3500 pages of deposition. I think that one there was like four or five days worth with three opposing attorneys beating on me every day. If I said that back then, then I misspoke and I would like to correct that today, then.

(*Id.* at 157.)

While Boneau's "corrected" testimony conveniently supports Medtronic's theory that ACS had "saturation exposure" to the Boneau stent before Lau's invention, it completely contradicts Boneau's prior sworn testimony, as well as Dr. Stertzer's testimony at trial. Specifically, Dr. Stertzer testified that the first "substantive" presentation he gave to ACS about the Boneau stent was in August or September of 1990. (*Id.* at 63-64, 98-99.) Thus, on this point—like many others—Boneau's testimony stands alone, uncorroborated, and largely contradicted by the record.[3]

[3] Boneau made other assertions at trial that are completely uncorroborated, even by his own former partner, Dr. Stertzer. For instance, Boneau claimed he had business meetings with Dr. Schneiderman in 1989, during which Dr. Schneiderman allegedly told him that ACS "would never use metal stents in human coronary arteries." (D.I. 670 at 117.) Yet Dr. Stertzer never mentioned any such meetings, nor did he corroborate Boneau's testimony that ACS's engineers affirmatively "denied" working on an internal stent program. In its brief, Medtronic asserts that, because ACS did not call Dr. Schneiderman to rebut Boneau's testimony, ACS somehow acquiesces to it. That is incorrect. There simply was no reason for ACS to spend its allotted six hours rebutting Boneau's uncorroborated testimony on irrelevant issues, e.g., whether Dr. Schneiderman told him ACS would never use metal stents. It is worth noting, though, that Medtronic deposed Dr. Schneiderman for three days and found *nothing* in that testimony that it could read into the record to corroborate Boneau's story. Thus, Dr. Schneiderman obviously disputes Boneau's version of events.

C. The Boneau Patent Application

Boneau filed his patent application on August 24, 1989. (AX-18.) At some point, he provided a copy of the application to ACS. That Mr. Boneau did so is not surprising, given that he was essentially inviting ACS to license or acquire the Boneau stent technology, including the relevant intellectual property. It is likewise not surprising that ACS asked its outside patent counsel, Edward Lynch, to take a look at the patent application Mr. Boneau was offering for sale or license. Mr. Lynch did so in January and March of 1990 for a total of seven hours. (D.I. 671 at 532-34.) While Medtronic asks the Court to infer that Mr. Lynch's review was precipitated by a panicky "concern about the Boneau stent" (D.I. 683 at 9), the trivial amount of time involved simply does not support such an inference.

The Boneau application discloses a stent comprising a cylindrical zig-zag structure that is nearly identical to the prior-art Gianturco Z-stent. (*See* Exhibit B; *see also* D.I. 670 at 192-93; D.I. 637 at 1558.) The specification explains that, while the stents can be used in multiples, each should be long enough to function as a stand-alone stent:

> The stent 10 will preferably be of sufficient length as to maintain its axial orientation within the vessel without shifting under the hydraulics of blood flow (or other fluid flow in different types of vessels), while also being long enough to extend across at least a significant portion of the affected area. At the same time, the stent should be short enough as to not introduce unnecessarily large amounts of material as might cause undue thrombosis.

(AX-18, col. 5:17-25.) Consistent with that description, the application describes "[p]reliminary testing of stents having a length between 3.5 millimeters and 4.5 millimeters." (*Id.* at col. 5:31-36.)

At trial, ACS called Dr. Jerome Segal to help explain the teachings of the Boneau application. (D.I. 671 at 564-71; *see also* D.I. 637 at 1558-77.) Dr. Segal is a practicing interventional cardiologist and the former Director of the Cardiac Catheterization Laboratory at The George Washington University. (D.I. 633 at 360, 365-66.) Currently, he is the CEO of Medluminal Systems Inc., a medical-device company that is actively engaged in developing products in the interventional-cardiology field. (*Id.* at 359-60.) Dr. Segal has nearly twenty years of medical-device design experience (*Id.* at 368-69) and is a named inventor on at least sixteen issued U.S. patents for various cardiovascular devices (*Id.* at 377).

Dr. Segal testified that the Boneau application teaches "the use of one or more individual stents, which are *functional stents*" and that "one of the primary principles of the Boneau patent is that you *don't connect these stents together*." (D.I. 671 at 565.) With respect to the first point, Dr. Segal explained that those skilled in the art would understand that the range of lengths proposed by Boneau—i.e., "1 millimeter to 2 centimeters"—is not entirely functional:

> I mean, reading that as an interventional cardiologist, you would discount the low end of the range because you know that the low end of the range is not functional. Really, stents, to be a functional stent, you're starting at about 4 millimeters.

(D.I. 637 at 1565-66; *see also* D.I. 634 at 749-50 (Dr. Pearle on behalf of Medtronic: "stents are 5 to 40 mm in length").)[4] Medtronic's own expert, Dr. Wagoner, likewise agreed that some portion of Boneau's 1-20 mm range "might not work." (D.I. 670 at 186-88.) Similarly, Medtronic recently acknowledged in a brief filed with the Federal Circuit that "[o]ne skilled in the art reading the [Boneau] specification would realize that a stent as short as 1 mm would have difficulty functioning independently to maintain the patency of a diseased vessel." (Ex. A at 40.)

After identifying several significant errors in the Boneau application regarding the proposed placement of stents in the human anatomy, Dr. Segal concluded as follows:

> Q. Reading this patent alone, what does this reveal to you about the author of the passage?
> A. That probably he doesn't know a lot about the implantation of stents.

(D.I. 637 at 1564.) Dr. Segal's conclusion is, in fact, correct. (*See* D.I. 459 at 5 (explaining that Boneau's "only real contact with stents had been his work some time earlier as a machinist").)

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[4] Professor Saigal and Dr. Wagoner (neither of whom is a stent expert) testified that they found nothing in the stent literature that says a 1-2 mm ring would *not* work as a stand-alone stent. (D.I. 671 at 335; D.I. 670 at 169.) That testimony, however, does not prove that a 1-2 mm ring *would* work as a stent. Indeed, Dr. Stertzer conceded he has "no data" showing that a 1-2 mm zigzag ring would function as a stent. (D.I. 670 at 60.) Boneau's testimony that he made and "bench tested" stents as short as 2.2 mm (*id.* at 112-13) is irrelevant because (1) it is uncorroborated (as is his undated "size chart" (DTX-1319)) and (2) he is not qualified to opine as to whether his alleged "bench test" proved clinical functionality.

Regarding the second point—that Boneau teaches away from connecting stents—Dr. Segal pointed to several passages in the Boneau application that emphasize the advantage of using multiple, short, unconnected stents rather than a single, longer stent. (D.I. 671 at 567-68; *see also* D.I. 637 at 1572-77.) For example, the application expressly criticizes "the relatively long length" of some prior art stents because their length "has made it difficult to treat curved vessels." (AX-18, col. 2:68-3:4.) In contrast, the Boneau application advocates the use of short, *unconnected* stents to enable the treatment of curved or S-shaped vessels. (*Id.* at col. 3:39-40.) Medtronic's expert, Professor Saigal, agreed with that point:

> Q. And you acknowledge that the Boneau patent shows only unconnected stents?
> A. Correct.
> Q. There's no teaching or enablement of connecting stents together? Do you agree?
> A. That is right.

(D.I. 636 at 1419.)

Regarding the issue of "L<D," Professor Saigal asserted (incorrectly) that the Boneau application discloses L<D in all three states of the stent, i.e., as-manufactured, crimped, and expanded. (D.I. 671 at 339.) That argument, however, was merely an afterthought devised by Medtronic when it realized that, by asserting Palmaz '417 as an *anticipation* reference, it had effectively destroyed any chance it ever had of arguing that Boneau is anything more than cumulative to Palmaz '417.

To avoid this thorny dilemma, Medtronic simply did what has become its hallmark in this litigation—it flip-flopped. Specifically, during the liability trial in February, Professor Saigal testified that Palmaz '417 satisfies the "L<D" requirement because it illustrates a stent whose components have L<D, albeit only "in the expanded state." (D.I. 636 at 1339, *see also id.* at 1340 ("Again, to emphasize, this is all in the *expanded state* for this particular stent.").) Indeed, Medtronic argued vehemently to the Court—both orally and in writing—that Palmaz '417 *anticipates* the asserted claims of the Lau '154 patent and thus, as a matter of law, fully discloses the complete combination of features (including L<D) required by those claims. (D.I. 637 at 1744; D.I. 618; D.I. 627.) Then, just *three months later*, Medtronic put the same expert on the stand (Professor Saigal) to opine that Palmaz '417 is *not* a "complete

combination of features as it relates to the Lau patents" because it discloses L<D "only in the expanded state." (D.I. 671 at 339; *see also* D.I. 683 at 26-28.) According to Medtronic's new argument, Boneau is a "more complete" reference than Palmaz '417 because it allegedly discloses L<D in all *three* states. (*See* D.I. 683 at 30-31.)

Even putting aside Professor Saigal's inconsistent testimony and Medtronic's improper construction of "cylindrical elements,"[5] Medtronic's new argument suffers from another fatal flaw. Namely, the Boneau application does *not* disclose L<D in all three states. Instead, because those skilled in the art would understand the shortest functional Boneau stent to be approximately 4 mm in length (D.I. 637 at 1565-66), Boneau does not disclose L<D at all, let alone in all three states. Dr. Segal thoroughly explained that point at trial (D.I. 671 at 578-79), and his testimony was not rebutted by anyone skilled in the art.

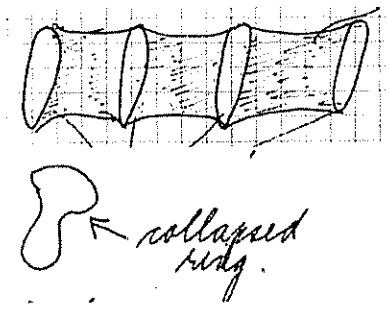
D. Lau's Invention

Lilip Lau began working at ACS in July of 1989. Contrary to Medtronic's assertion that he was "fresh out of college" (D.I. 683 at 7, 11), Mr. Lau had in fact completed a master's degree at Case Western Reserve University (D.I. 671 at 422) and had acquired approximately four years of medical-device design experience, both at MIT and Case Western (*Id.* at 422-23). Before beginning the process of designing a new stent for ACS, Mr. Lau first learned about some existing designs, specifically the Palmaz and Schatz stents, the Wallstent, the Gianturco-Roubin stent, and several of Dr. Sigwart's designs. (*Id.* at 427.) Mr. Lau did not learn about the Boneau stent at that time. (*Id.* at 428). Indeed, there is no credible evidence that *anyone* at ACS knew the details of Boneau's design in July of 1989. (D.I. 670 at 63-64, 98-99.)

Unlike Mr. Boneau, Mr. Lau carefully recorded his research efforts in a series of lab notebooks, each page of which was signed, dated, and witnessed. (D.I. 671 at 436-39.) Thus, it is possible to tell with considerable accuracy when he conceived of certain ideas.

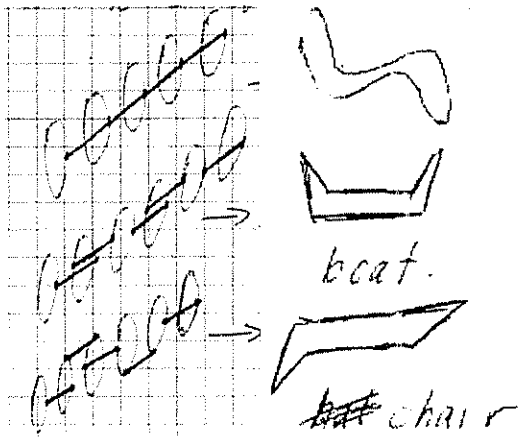
[5] ACS addresses Medtronic's erroneous and untimely claim construction in ACS's response to Medtronic's renewed JMOL motion. (D.I. 673.)

By July 17, 1989—long before Boneau provided ACS with any prototypes or substantive information about his stent and, indeed, before Boneau had even filed his patent application (let alone provided a copy to ACS)—Lilip Lau independently conceived of using multiple undulating, balloon-expandable, metal rings to hold open a diseased artery. (D.I. 671 at 443-45.) Those undulating or "collapsed" rings formed the ribs of what Mr. Lau called the "hoop and stocking" design, which consisted of expandable rings covered by a fine, flexible mesh. (AX-798 at 1-2.)



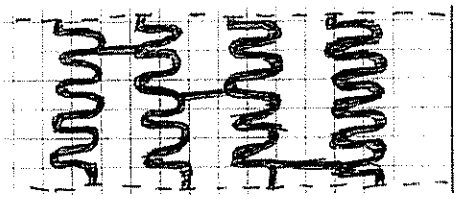
Lau's July 17, 1989 design included metal "rings" that were "collapsed for a reduced profile" during delivery then balloon-expanded to a "desired operating configuration." (AX-798 at 1-2.)

By February 22, 1990—at least a month before Boneau allegedly came up with his "suture stent" (D.I. 670 at 137)—Mr Lau independently conceived of connecting multiple balloon-expandable, undulating rings together to form a stent. (AX-799 at 34.) Specifically, he envisioned "cross bars" between the individual rings in either a straight or alternating pattern, substantially as shown in Figs. 7-10 of the Lau patents. (*See* D.I. 671 at 448-50.) The rings, as Mr. Lau explained in his February 14, 1990 entry, were "made to be expandable in diameter" by folding them into one of several zigzag patterns so that, as "the balloon is inflated, the bends in the rings straighten, allowing the diameter to increase." (AX-799 at 28.)



Lau's Feb. 22, 1990 design included a plurality of radially expandable, zig-zag rings (right), connected by "cross bars" (left). (AX-799 at 28, 34.)

By March 2, 1990, Mr. Lau had further refined his idea to "a very specific design" comprising "collapsed" or undulating rings connected by cross bars, all cut from a single tube. (AX-799 at 42; D.I. 671 at 451-56.) Lau's drawings from that date also became the basis for several figures in the Lau patents. (*Id.* at 453-54.) By



Lau's Mar. 2, 1990 design. (AX-799 at 42.)

June 5, 1990, Lau had developed engineering drawings of an out-of-phase version of this stent (AX-800 at 36), and he and his team were "well on [their] way to building prototypes" (D.I. 671 at 456-57).

All of this research and design work took place *before* Dr. Stertzer gave his first substantive presentation to ACS about the Boneau stent in August or September of 1990. (D.I. 670 at 98-99.) It also took place *before* Boneau allegedly disclosed his "suture stent" idea to ACS:

> Q. You would agree, sir, that the first time you could have told ACS about your suture stent idea was in August of 1990, is that right?
> A. Yes.
> Q. And so if ACS already had the idea of connecting stents before that time, the idea didn't come from you, did it?
> A. Couldn't be.

(*Id.* at 153-54.) Lau's research likewise took place *before* Boneau allegedly disclosed the idea of implanting stents in a "crown-to-crown" configuration [6]

In its brief, Medtronic seizes upon Lau's March 2, 1990 notebook entry as a watershed event that allegedly set in motion a vast conspiracy at ACS, and at the Fulwider and Crosby law firms, to simultaneously cheat Mr. Boneau and defraud the PTO. According to Medtronic, the "circumstantial evidence . . . *compels* the conclusion that on or about Friday, March 2, 1990, Mr. Lau reported his invention to Ms. McDermott . . . who . . . was concerned that either Mr. Lau's design would infringe whatever patent issued from the Boneau application or Mr. Lau's design would not be patentable in view of Boneau." (D.I. 683 at 10, emphasis added.) According to Medtronic's fictional account, Ms. McDermott then immediately asked Mr. Lynch for an opinion on the Boneau application, "presumably on infringement and/or patentability," which Lynch allegedly delivered on March 12. (*Id.*)

The evidence simply does not support Medtronic's theory that Friday, March 2, 1990, was a bombshell day at ACS that sent Ms. McDermott scrambling for an emergency opinion on whether Lau's connected-ring design was patentable over Boneau. For instance, only two of the six notebook pages on

[6] Boneau could not recall whether he disclosed the alleged "crown-to-crown" concept to ACS in 1989. (D.I. 670 at 144.) He testified, however, that he disclosed *nothing* in 1989 that was not in his patent application (*id.* at 145), and it is undisputed that Boneau's application does not disclose implanting stents in a crown-to-crown orientation (*id.* at 144).

that day even relate to Lau's connected-ring design; the remainder relate to an improved PTCA balloon. (AX-799 at 37-40.) Similarly, Lau's entries the following Monday, March 5, relate to an entirely *different* stent idea, namely a Sigwart "locking ring" design, to which Lau devoted five pages. (*Id.* at 47-50.) Lau continued to explore the locking ring design on March 15, March 22, March 26, April 11, April 23, April 30, and May 1, devoting dozens of pages to that idea. (*Id.* at 57-58, 68-71, 75-76, 112-116, 134, 146-47.) In contrast, Lau did not revisit the connected-ring design again until May 10 (AX-800 at 29-30), more than two months *after* the alleged "March 2" conspiracy was supposedly hatched.

There are other problems with Medtronic's conspiracy theory. For one, Ms. McDermott—the alleged ringleader of the conspiracy—did not even recall Mr. Boneau's name, let alone anything about his stent.[7] (D.I. 670 at 269.) Likewise, Medtronic has provided no evidence that Ms. McDermott was involved in any substantive way with the Lau patent prosecution. (*See id.* at 272-73.)

Another problem is that Mr. Lynch spent a paltry 2.5 hours evaluating the Boneau application on March 12 (DTX 1010), hardly enough time to provide an opinion on infringement and/or patentability as Medtronic asks the Court to presume. Indeed, it is unclear why Medtronic is asking the Court to *presume* anything, since Lynch's billing records clearly explain what he did, namely: "review and study of ESS application and claims as filed and conference with E. McDermott regarding the prior art and the scope of the claims." (*Id.*) Those actions are entirely consistent with the fact that Boneau was shopping his patent application to ACS at that time. They are *inconsistent*, however, with Medtronic's theory that Mr. Lynch provided an opinion as to whether *Lau's design* was patentable over the Boneau application. Had Lynch actually provided such an opinion, he first would have had to review and understand Lau's invention, and there is no indication that he did so during his 2.5 hour review.

E. The 1990 Feasibility Study

On July 31, 1990, Lilip Lau and Fred Khosravi authored a feasibility study titled "A Review of ACS's Implantable Coronary Stent Concepts." (AX-268.) In the study, they considered five ACS

[7] Contrary to Medtronic's assertion that she is "uniquely in the control of ACS" (D.I. 683 at 39), Ms. McDermott is no longer affiliated with ACS. (D.I. 670 at 275-76.)

designs, including Lau's connected-ring design, and five non-ACS designs, including the Boneau stent. (*Id.*) Based on a qualitative review of those ten designs, they recommended pursuing development of Lau's connected-ring design, and they ranked Boneau's design last. (*See* D.I. 671 at 387-91.) According to Medtronic, the feasibility study proves that (1) "Mr. Lau had access to the Boneau application, either directly or indirectly, through Ms. McDermott" (D.I. 683 at 11) and (2) "ACS concealed [from Boneau] that it had already evaluated the Boneau stent and decided to develop a very similar design" (*id.* at 3). Neither allegation, however, is supported by the evidence.

The feasibility study, far from proving that Lau had access to the Boneau application, actually proves the opposite. As Michael Orth (then manager of ACS's Stent Business Unit) explained, many of the characteristics attributed to the "Boneau stent" in the feasibility study were, in fact, wrong. (D.I. 671 at 392-93.) Indeed, contrary to Medtronic's assertion that Lau and Khosravi "included a sketch of a Boneau stent in the report" (D.I. 683 at 11), Mr. Lau testified that the sketch was actually a tracing from the *Gianturco* patent:

> Q. Why did you use the Gianturco for the Boneau stent representation?
> A. Well, for one, *we obviously didn't have a Boneau stent*. Otherwise we would have used it. It would have been much easier to. And, secondly, in our minds, kind of a structure, from what we understood of, you know, the Boneau stent and of the Gianturco stent, structurally, [to] stent designers, they're the same thing

(D.I. 671 at 468-69.) Moreover, the description of the "Boneau" stent in the 1990 feasibility study does not include *any* of the features Medtronic now claims are essential to the "Boneau prior art," namely short rings with L<D, arranged "crown-to-crown" and sutured together. (AX-268 at ACS-004562.)

Mr. Lau testified very clearly that he never saw the Boneau patent application (*Id.* at 507), and Mr. Orth corroborated that fact (*Id.* at 392). Yet Medtronic insists Lau's testimony "is not credible" because, "[g]iven the detail of the [feasibility study] and that there was no publicly available information on the Boneau stent in July 1990, the *only way* Mr. Lau could have prepared the [feasibility study] was if he had access to the Boneau application." (D.I. 683 at 18, emphasis added.) That attack on Mr. Lau's credibility is simply absurd. First, as explained above, much of the information about the Boneau stent in

the feasibility study—including the sketch itself—was incorrect, an uncontested point that eviscerates Medtronic's theory that Lau had access to the Boneau application.[8] Moreover, Medtronic's assertion that "there was no publicly available information on the Boneau stent" flies in the face of its own prior admission that "work on the Boneau stent was *open and obvious*" (AX-835A at 14-15) and that "Boneau and Stertzer's work on the Boneau stent was *no secret*" (*id.* at 16-17). *See also id.* at 8-9 (balloon-expandable zig-zag stent design was "publicly known . . . in the late 1980's") and 22-23 (Boneau's work was "publicized" to "many thousands of physicians" in 1990).)

Medtronic next alleges that ACS "concealed" the results of the feasibility study from Boneau and Stertzer and staged an elaborate "deception" to "dupe" them into revealing additional details about their stent. (D.I. 683 at 3, 34.) That allegation, however, is both irrelevant and factually unsupported. First, whether or not ACS informed Boneau and Stertzer about the feasibility study or ACS's internal stent program is a moot point, for Medtronic has not shown they were *entitled* to such information. In any event, there is no credible evidence that ACS engaged in any sort of "deception" as Medtronic alleges. That allegation is based solely on Boneau's testimony that ACS's engineers "flat-out denied" working on an internal stent project. (D.I. 670 at 136.) Mr. Orth testified, however, that he *never* concealed that fact (D.I. 671 at 397), and Mr. Khosravi testified that he *specifically informed* Dr. Stertzer about ACS's stent program:

> Q. Do you recall what else you talked about during this visit, other than the Boneau stent?
> A. I recall that we provided him with a brief update of some of [the] internal development activities at ACS.
> Q. What did you tell him about your internal development activities?
> A. I do recall that we did talk about our direction with the stents and let him know we have an internal program, but that's the extent of—the extent of what I do recall.

[8] Exhibit C shows a comparison of the Gianturco Z-stent and the sketch identified in the feasibility study as "Boneau." Medtronic cannot deny they are virtually identical, yet it attacks Lau's credibility because he did not specifically remember reading the Gianturco patent. (D.I. 683 at 19.) Whether or not Lau read the entire Gianturco patent is irrelevant, for the fact is he subjectively believed (correctly, it turns out) that Boneau was simply a balloon-expandable version of Gianturco.

(D.I. 670 at 287-88.) Dr. Stertzer did not deny receiving this information about ACS's stent program. In fact, he conspicuously did *not* corroborate Boneau's testimony that ACS's engineers "flat-out denied" working on stents. Thus, once again, Boneau's testimony stands alone, uncorroborated, and flatly contradicted by the record.

Although the feasibility study does not prove Medtronic's conspiracy theory, it does prove one relevant point (which Medtronic conveniently ignores). Namely, it shows that Mr. Lau and others at ACS believed that the Lau and Boneau stents were *very different* designs, literally ranking at opposite ends of the scale. Lau, Khosravi, and Orth all testified to that point. (*See* D.I. 670 at 289; D.I. 671 at 394-95, 476-83.) As Mr. Lau explained, the Boneau stent "was just—I mean, it was just a very different stent idea, you know. Right or wrong, it was just different." (D.I. 671 at 483.)

F. Stertzer and Boneau's First Substantive Presentation to ACS in August or September of 1990

Stertzer and Boneau gave their first formal presentation to ACS in late August or early September of 1990 (D.I. 670 at 98-99), during which they provided prototypes of the Boneau stent (*id.* at 156). According to Medtronic, the fact that ACS even invited such a presentation is further evidence of a vast conspiracy to cheat Mr. Boneau and defraud the PTO. Specifically, Medtronic contends that, "[b]ased on the timeline of events, the *only logical explanation* is that ACS invited Mr. Boneau back because ACS recognized the similarities between Mr. Boneau's design and Mr. Lau's design and wanted as much information about the Boneau stent as possible . . ." (D.I. 683 at 13, emphasis added.) Of course, that theory ignores the testimony of Mr. Orth, a disinterested ex-ACS employee who provided not only a "logical explanation" but an *unrebutted first-hand account* as to why Stertzer and Boneau were invited back:

> Q. Now, let me ask you: You had already ranked the Boneau technology ten of ten in your feasibility study. Why did you now spend your resources and those of your engineers further evaluating these prototypes?
> A. Well, at the time we did the feasibility report, we had, you know, little to no information on the Boneau stent. We didn't—we had to make assumptions about what we thought it was and there was the possibility that if, when we got these stents and looked at them, that

> our assumptions would be incorrect and could change the outcome of, you know, those tests.

(D.I. 671 at 403.) Mr. Orth explained that the goal of the meeting and the evaluation was to "give [the Boneau stent] a fair and thorough review and make a definitive decision as to whether [ACS] wanted to move forward with this technology or not." (*Id.* at 396.) The reason a "definitive decision" was needed was that Dr. Stertzer—an important customer and ACS consultant (*id.* at 395)—"had not gotten a decision yes or no from ACS" regarding the Boneau stent. (*Id.* at 396-97.)

There is no evidence that the 1990 meeting was part of an elaborate plot, as Medtronic contends, to purloin additional information about the Boneau stent from Dr. Stertzer and Mr. Boneau.

1. The Boneau Stent Concept, as Explained to ACS

The explanation of the Boneau stent provided by Dr. Stertzer and Mr. Boneau in 1990 was consistent with how a person skilled in the art would understand the Boneau application. Namely, they explained that one or more stand-alone Boneau stents, measuring 4-7 mm in length, could be implanted, alone or in multiples, to treat an abrupt or threatened closure. (*See* D.I. 671 at 476-81.) As Mr. Lau recalled, the idea was to provide a very minimal amount of metal to tack up a flap or tear. (*Id.* at 477-78.) Similarly, Mr. Orth recalled that the selling point of Boneau's design was that, by using short, unconnected units to cover longer lesions, you could create "almost any length stent you needed to and decrease the amount of inventory you would have to carry in the hospital." (*Id.* at 399.) Mr. Khosravi had a nearly identical recollection. (D.I. 670 at 286.) Dr. Stertzer likewise confirmed that each Boneau stent "could be used as a *stand-alone stent*," either alone or in "multiple units." (*Id.* at 93-94.)

Consistent with the recollection of Messrs. Lau, Orth, and Khosravi, it is undisputed that each of the Boneau prototypes provided to ACS was, in fact, a stand-alone stent measuring 4-7 mm in length. (D.I. 671 at 398, 479; *see also* D.I. 670 at 94-95.)

2. No Disclosure of the Alleged "Suture Stent"

Mr. Boneau claims he conceived the so-called "suture stent" in March of 1990, while working side-by-side with Dr. Stertzer in Argentina. (D.I. 670 at 137.) Yet there is no corroborating evidence:

Q. Do you have any documents to support that testimony, sir?
A. No.
Q. Do you keep a lab notebook?
A. No.
Q. Do you ever write your own work down?
A. No.
Q So, other than your sworn testimony here today, we have no other evidence that you came up with this idea of connecting stents together with sutures; is that right?
A. That's correct.

(*Id.* at 152.) Indeed, the one person Medtronic could have asked to corroborate Boneau's "suture stent" story—Dr. Stertzer—*conspicuously failed to do so*. It is very telling that Dr. Stertzer—Boneau's former partner and the very person Boneau was working with in Argentina when he allegedly conceived the idea—had absolutely nothing to say about the "suture stent."

Far from corroborating Boneau's testimony, the objective evidence in this case strongly contradicts it. To begin with, Boneau never filed a patent application on the "suture stent" concept. (*Id.* at 154-55.) Indeed, it was not until October of 1994 that he even applied for the *general* concept of connecting Boneau stents together (AX-216), more than *four years* after he allegedly conceived the idea. When asked why he delayed filing for so many years, Boneau said he had become "clinically depressed" in March of 1990 and, for about two years, "flat-out didn't do much of anything, let alone try to file a patent." (D.I. 670 at 162-63.) Yet he met with ACS in September of 1990 (contrary to his testimony that he "flat-out didn't do much of anything"), and his description of those meetings—i.e., "kind of like fun and work . . . [j]ust a real fun project, a real fun thing" (*Id.* at 135)—simply does not square with a person so severely depressed that he couldn't file a patent application.

Boneau claims he disclosed his "suture stent" to ACS in September of 1990. Yet, once again, there is no corroborating evidence for that claim:

Q. Do you have any documents showing that you disclosed this to ACS in 1990?
A. No.

* * * *

Q. So there's no evidence at all?
A. No.

(*Id.* at 153.) Moreover, Boneau previously testified that he could not recall providing "*any* valuable

information" to ACS in 1990 that was not already in his patent application (*id.* at 149-50), and it is undisputed that his application does not disclose connecting stents (D.I. 636 at 1419).

Boneau's testimony was also flatly contradicted by the very people to whom he allegedly disclosed his "stuture stent." For instance, Mr. Lau testified as follows:

> Q. Were these stents that they discussed ever told to you that they were connected in any way?
> A. Never.

(D.I. 671 at 479.) Mr. Orth and Mr. Khosravi were equally clear on this point. (*Id.* at 401-02, 286-87.)

Finally, Dr. Stertzer—Boneau's own former partner—was *conspicuously silent* about the alleged disclosure of a "suture stent" to ACS in 1990. Thus, once again, Boneau's testimony stands alone, uncorroborated, and contrary to the record.

3. No Disclosure of the Alleged "Crown to Crown" Concept

Medtronic contends that Dr. Stertzer had a "tradition" in 1988-89 of implanting Boneau stents "crown-to-crown" and that Boneau disclosed this practice to ACS during the meetings in 1990. (D.I. 683 at 2-3.) There is no evidentiary support for that assertion, however.

To begin with, there is no documentation of Dr. Stertzer's alleged crown-to-crown "tradition" in 1988-89. Although Medtronic brought four angiograms to trial that allegedly show crown-to-crown placement (DTX-495), those angiograms (which Medtronic *never* identified as prior art in a § 282 notice) prove absolutely nothing:

> Q. Now, Doctor, in looking at those four angiograms, can you tell what the date was on those angiograms?
> A. I don't believe so, no
> Q. There's no date on any of those pictures, is there?
> A. I don't believe so, no
> Q. Do you see one?
> A. No, I don't.
> Q. Okay. And as you are testifying here today, you are not sure whether those are the angiograms that Mr. Boneau took to ACS at any time, are you?
> A. You mean with absolute certainty?
> Q. With enough certainty to testify under penalty of perjury.
> A. No.

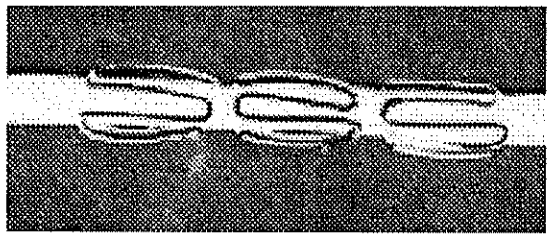
(D.I. 670 at 85.)

Mr. Boneau testified that he showed a different set of angiograms (DTX-497) to ACS's engineers in 1990, but he conceded it was impossible to tell from those angiograms whether the stents were oriented crown-to-crown:

> Q. Now, is it your testimony that this particular photograph—these particular photographs show crown to crown placement of your Boneau stent?
> A. No, that's not what I said. What I said was, I believe what I testified to earlier was that it appeared or if *tradition* held there, that they *should* be crown to crown or out of phase.
> Q. But you can't tell from the photograph?
> A. I don't think anyone can.

(*Id.* at 158-59.)

The only other document Medtronic produced to support its "crown-to-crown" argument is DTX-227, which Mr. Boneau claimed he showed to ACS's engineers in 1990 (D.I. 670 at 127-28). That document, however, actually *disproves* Medtronic's theory. Namely, DTX-227 shows three Boneau stents that are mounted both out-of-phase *and in-phase* on the same balloon. Thus, far from supporting the alleged "*importance* of implanting multiple stents in a crown-to-crown or 'out of phase' configuration" (D.I. 683 at 13, emphasis added), DTX-227 actually proves that "crown-to-crown" placement was not important at all.

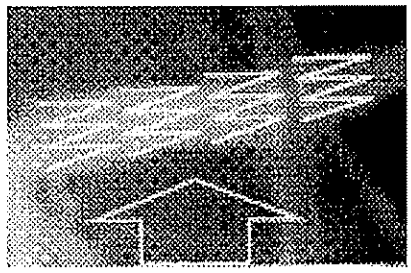


Detail from DTX-227 (allegedly shown to ACS in 1990), showing two Boneau stents arranged out-of-phase (left) and two arranged in-phase (right).

In fact, the evidence at trial showed that neither Boneau nor Stertzer considered "crown-to-crown" placement a necessary or important feature of their technology. For instance, Boneau failed to even mention it in his patent application, despite a legal requirement to disclose the best mode of practicing his invention. (D.I. 670 at 144.) Although he suggested that he only learned about the "crown-to-crown" concept after he filed his application (*id.* at 151), that suggestion is hard to believe given the extent to which he allegedly worked side-by-side with Dr. Stertzer during various clinical studies (*id.* at 122). Indeed, if Boneau himself did not perceive the alleged importance of implanting his stents "crown-

to-crown" after *months* of working closely with Dr. Stertzer, the inference that ACS's engineers perceived it just by looking at a few angiograms during a meeting seems quite far-fetched.

The "crown-to-crown" concept is also conspicuously absent from Dr. Stertzer's contemporaneous writings. For instance Dr. Stertzer's article, "The Applied VE Micro Stent," depicts a "[g]raphic overlay of four separate AVE type stents units placed in tandem [in] April 1989." (AX-62.) Yet those Boneau stents are clearly arranged *in phase* rather than "crown-to-crown." Nowhere in the article does Dr. Stertzer indicate to other physicians that crown-to-crown placement is clinically important, e.g., to prevent "significant gaps" between the stents as he testified at trial. (D.I. 670 at 43-44.)



Detail from Dr. Stertzer's article, depicting "four separate AVE type stents" implanted in 1989 in an *in-phase* orientation. (AX-62.)

Even if the alleged crown-to-crown "tradition" existed, there is no evidence that it was specifically conveyed to ACS in 1990. The best Boneau could say is that it "should" have been conveyed if "tradition held" (D.I. 670 at 158-59), and Stertzer simply could not remember one way or the other (*id.* at 67). Messrs. Lau and Orth, on the other hand, both recalled *nothing* about a "crown-to-crown" orientation being discussed. (D.I. 671 at 400, 481.) And DTX-227 affirmatively *proves* that "crown-to-crown" placement was not emphasized as being important during the 1990 meetings.

G. Prosecution of the Lau Patents

The original Lau application was filed on October 28, 1991. (AX-2586 at LJA 91.) At that time, Mr. Lynch was the primary attorney of record. (*Id.* at LJA 127.) Though Mr. Lynch had previously been employed at Fulwider, Patton, Lee & Utecht, he had since left that firm to join Crosby, Heafy, Roach & May when the Lau application was filed. As discussed above, Mr. Lynch had previously spent only seven hours—a year and a half earlier while at Fulwider—on a matter involving the ESS (Boneau) patent application. He testified, however, that he had no recollection of bringing the ESS file with him to Crosby and, indeed, did not recall ever looking at that file again after March of 1990. (D.I. 671 at 534.) Mr. Lynch also testified that he did not "recall thinking about the ESS application when [he] prepared [the

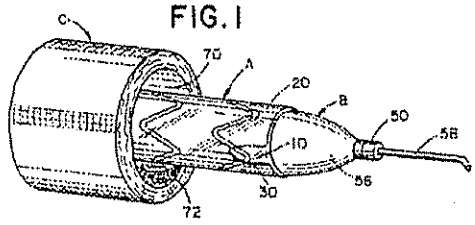
Lau] application." (*Id.* at 537.) Thus, there is no evidence that Mr. Lynch had contemporaneous knowledge of the ESS application when he prepared and filed the Lau patent application.

Mr. Lynch did not perform a prior-art search, nor did he file an information disclosure statement ("IDS") with the PTO. (*Id.* at 537, 539.) That is because, shortly after the Lau application was filed, the entire prosecution matter was transferred back to Fulwider, and Mr. Lynch had no further involvement with it. (*Id.* at 541.) At Fulwider, John Nagy took over prosecution of the Lau application.[9]

During prosecution of the original Lau application, ACS disclosed over a hundred prior-art references, including Palmaz '417 (AX-160), Gianturco '658 (AX-40), MacGregor '071 (AX-2586 at LJA 1496-1503), Hillstead '516 (*id.* at LJA 138-43), Hillstead '536 (*id.* at LJA 160-68), Wolff '404 (DTX-14), Lee '917 (DTX-1000-79), and the European counterparts of Schatz '984 (AX-54) and Gianturco '706 (DTX-1000-53). For the Court's convenience, drawings of some of those prior-art stents are shown in Exhibit D.

The Lee '917 patent—cited in the *very first* IDS (AX-2586 at LJA 136)—discloses an intraluminal graft that was "designed with the coronary artery in mind." (DTX-1000-79, col. 6:59-61.) As shown in Fig. 1, one embodiment consists of "a plurality of separate expandable ring-like scaffold members" (*id.*, col. 2:36-37), each of which "includes a plurality of angled straight sections 32 and 34 which are connected at bends 36," as shown in Fig. 5 (*id.*, col. 5:20-21).[10] The Lee stent is "mounted on a standard commercially available balloon catheter" (*id.*, col. 5:62-63), such that the

FIG. 1



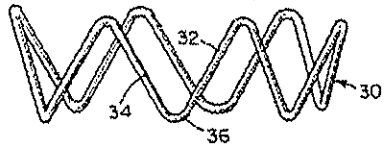


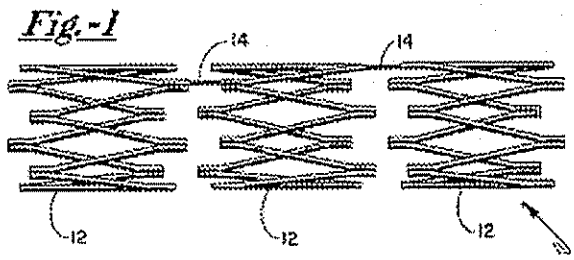
FIG. 5

[9] Medtronic chose not to depose Mr. Nagy during this litigation, despite having ample opportunity to do so. Medtronic also did not include Mr. Nagy's name in the Supplemental Joint Pre-trial Order, filed just one month before the inequitable conduct trial.

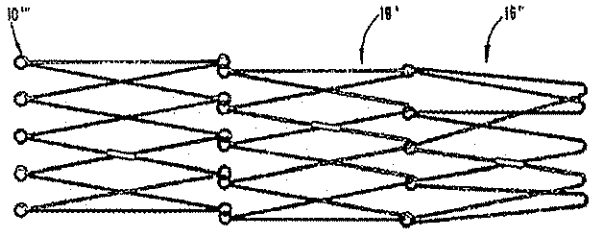
[10] The scaffold members of Lee can by positioned between two flexible tubes (DTX-1000-79, col. 5:11-21), or they can be mounted on the inside or the outside of a single flexible tube (*id.*, col. 7:21-28).

scaffold members are "deformed beyond their elastic limit when the graft is expanded" (*id.*, col. 2:51-53). Dr. Segal further explained that, based on the description in Lee, the scaffold members shown in Fig. 1 are "between 1 millimeter and 2 millimeters in length" (D.I. 671 at 581) and have a "length less than diameter in all states" (*id.* at 583). That testimony was undisputed.[11]

ACS also submitted numerous references showing the "crown-to-crown" arrangement that Medtronic asserts Dr. Stertzer traditionally used. The Wolff '404 patent, for instance, clearly discloses such an arrangement. (*See also* Exhibit E.)



ACS also submitted at least one reference showing both a "crown-to-crown" orientation and the "suture stent" concept allegedly invented by Boneau in March of 1990. Specifically, ACS identified EP 0,423,916, a European counterpart to Gianturco '706 (*see* AX-2586 at LJA-0209), which discloses suturing together multiple Gianturco Z-stents, as shown here. Notably, that patent was filed several months *before* Boneau's alleged "suture stent" invention. (DTX-1000-53.)



As prosecution of the Lau patents progressed, ACS filed additional IDS forms, often identifying older references that had not yet been brought to the examiner's attention. For instance, on January 23, 1996, ACS identified five references with publication dates ranging from 1988 to 1993. (AX-2586 at LJA 1686-88.) Similarly, on March 19, 1997, ACS identified eight references with publication dates ranging from 1983 to 1992. (*Id.* at LJA 1772-75.) Indeed, the record reflects that, throughout the prosecution of the Lau patents, ACS routinely updated its disclosure of prior art to the PTO, often identifying references that were several years old. (*See, e.g., id.* at LJA 1704-06, 1800-02, 1871-97,

[11] Although Professor Saigal testified that the *overall* Lee graft has L greater than D (an irrelevant point since the Lau claims do not require the *entire stent* to have L<D), he did not dispute that each individual scaffold member has L<D in all states. (D.I. 671 at 368-69.)

2396-2417.) With the exception of the Boneau patent, however (submitted three years after it issued), Medtronic has not alleged that any of ACS's routine prior-art updates reflect inequitable conduct.

ACS cited the Boneau '331 patent on August 27, 1997 in an IDS that included just one other reference. (*Id.* at LJA 1800-02.) Thus, ACS did not "bury" Boneau amidst numerous references, nor did it try to avert the examiner's attention away from Boneau. Indeed, far from trying to *conceal* the Boneau reference—as Medtronic alleges—ACS called the Examiner's attention to it by submitting it with just one other reference and mentioning it in an interview. (*Id.* at LJA 1790.) All told, Boneau '331 was cited in three of the four Lau patents-in-suit ('167, '168, and '133) and, indeed, is listed on the face of those patents as one of the "U.S. Patent Documents" cited. (*See* AX-5, AX-6, AX-7.)

The Examiner duly considered Boneau and indicated his review by initialing the IDS form. (AX-2586 at LJA 1802.) But, contrary to Medtronic's assertion that Boneau is a "highly material" reference, the Examiner never issued a *single rejection* based on Boneau in any of the Lau patents-in-suit. Indeed, in the *fifteen* Lau patents that have issued since Boneau was cited in 1997, the PTO has *never* rejected a single Lau claim based on Boneau. (D.I. 671 at 360-02.) That is not to say, however, that the PTO has not issued any rejections. To the contrary, the PTO rigorously examined the Lau '167, '168, and '133 patents, issuing rejections over numerous references, including Schatz '332 (AX-2586 at LJA 1904, 2087), Sakura '587 (*id.* at LJA 2087), Israel '303 (*id.* at LJA 1999), Pinchasik '373 (*id.*), Karpovich SU 1457921A (*id.* at LJA 2390), and others. Yet there was not a *single rejection* over Boneau.

III. ARGUMENT

A. Statement of the Law

Inequitable conduct must be proven by clear and convincing evidence. Specifically, "[o]ne who alleges inequitable conduct arising from a failure to disclose prior art must offer clear and convincing proof of [1] the materiality of the prior art, [2] knowledge chargeable to the applicant of that prior art and of its materiality, coupled with [3] an intent to mislead the PTO." *Warner-Lambert Co. v. Teva Pharmaceuticals USA*, 418 F.3d 1326, 1342-43 (Fed. Cir. 2005) (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995)).

"The governing standard for materiality is the one in place when the pertinent events of the patent prosecution occurred." *Rhenalu v. Alcoa, Inc.*, 224 F. Supp.2d 773, 805 (D. Del. 2002). Here, the current version of 37 C.F.R. § 1.56 (which was adopted January 17, 1992, just ten weeks after the original Lau application was filed) was in effect when the first IDS was submitted in August 1992, and remained so throughout the Lau prosecution. It states, in part, that "information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and . . . [i]t establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim." 37 C.F.R. § 1.56(b).[12]

A reference is not material if it is "cumulative to information already of record" in the application. 37 C.F.R. § 1.56(b); *see also Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1440 (Fed. Cir. 1991) (applying the pre-1992 standard: "[A] patentee has no obligation to disclose an otherwise material reference if the reference is cumulative or less material than those already before the examiner.") A reference is considered cumulative, and therefore not material, when it "teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO." *Regents of the Univ. of Cal. v. Eli Lilly and Co.*, 119 F.3d 1559, 1574-75 (Fed. Cir. 1997).

Medtronic asserts—incorrectly—that a reference may be deemed material "even if it would not have actually led to a rejection of any claims in the application." (D.I. 683 at 25.) For that proposition, it cites *Gardco Mfg., Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1213 (Fed. Cir. 1987), and *Atofina v. Great Lakes Chem. Corp.*, 2005 U.S. Dist. LEXIS 7365 (D. Del. Mar. 16, 2005). Yet those cases merely hold that "[a] reference . . . does not have to render the claimed invention *unpatentable or invalid* to be material." *Atofina*, 2005 U.S. Dist. LEXIS 7365 at *70-71 (emphasis added); *accord Gardco*, 820 F.2d at 1213. That does not mean a reference can be material even though it would not support a *prima facie*

[12] Medtronic urges the Court to apply the pre-1992 standard (D.I. 683 at 26), which defined materiality in terms of whether "a reasonable examiner would consider [the reference] important in deciding whether to allow the application to issue as a patent." 37 C.F.R. § 1.56(a). That was not the prevailing standard, however, at the time the *pertinent* events of the prosecution occurred, i.e., the submission of the first IDS and the subsequent disclosures to the PTO. But since Medtronic has failed to prove inequitable conduct under *either* standard of materiality, the issue should be moot.

rejection. To the contrary, 37 C.F.R. § 1.56 clearly states that a material reference *must* either be capable of supporting a prima facie rejection or be inconsistent with an argument made by the applicant.

Medtronic also asserts that, once "Medtronic has established a prima facie case of materiality . . . the burden [shifts] to ACS to show that it acted in good faith." (D.I. 683 at 3.) That, too, is flatly contrary to the law. Medtronic bears the burden of proving, by clear and convincing evidence, *each prong* of inequitable conduct. *Warner-Lambert*, 418 F.3d at 1346. There is absolutely no support for Medtronic's assertion that it need only prove the materiality prong of inequitable conduct, whereupon the burden "shifts" to ACS to prove that it acted without deceptive intent. *See, e.g., Allen Organ Co. v. Kimball Int'l, Inc.*, 839 F.2d 1556, 1567 (Fed. Cir. 1988) ("[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct.") Indeed, that Medtronic would even suggest such an upside-down view of the law speaks volumes about the strength of its case.

Medtronic cites *Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc.*, 984 F.2d 1182, 1191 (Fed. Cir. 1993), for the proposition that ACS bears the burden of *disproving* deceptive intent in this case and that "ACS's [alleged] failure to offer any evidence of good faith establishes ACS's intent to mislead the PTO." (D.I. 683 at 35.) *Paragon* says no such thing. The issue in *Paragon* was whether the patentee had come forward with enough evidence *on summary judgment* to show a genuine issue of material fact regarding deceptive intent. Citing the summary judgment standard, the Federal Circuit made the unremarkable observation that: "KLM having made a prima facie case of inequitable conduct by satisfying *both elements thereof*, the burden shifted to Paragon to come forward with evidence which would require reassessment of the validity of the defense." 984 F.2d at 1191 (emphasis added).

Paragon does not support Medtronic's contention that a prima facie showing of materiality "shifts the burden to ACS to show that it acted in good faith." (D.I. 683 at 3.) To begin with, the summary-judgment mechanism of shifting the burden of *production*, i.e., to test for genuine issues of material fact, does not apply here. Essentially, Medtronic seeks (improperly) to replace its clear and convincing burden of *persuasion* with the much lower "prima facie" burden of *production* applicable

under Fed. R. Civ. P. 56.[13] While "[t]he prima facie burden is quite easy to meet," *Hodgens v. General Dynamics Corp.*, 144 F.3d 151, 165 (1st Cir. 1998), Medtronic's burden in this case is much, much higher.

In summary, before a patent can be found unenforceable for failure to cite a reference, a two-part test must be satisfied by clear and convincing evidence. First, the party alleging unenforceability must prove *both* (a) that the uncited reference "meets a threshold level of materiality," and (b) that the reference was withheld because of "a threshold level of intent to mislead the PTO." *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1327 (Fed. Cir. 1998). Only after those threshold requirements are proven by *clear and convincing evidence* does the Court proceed to the second part of the test, namely, "weigh[ing] materiality and intent" to determine whether, "[i]n light of all the circumstances, . . . the applicant's conduct is so culpable that the patent should be held unenforceable." *Id.* Thus, the "balancing test" that Medtronic refers to repeatedly in its brief occurs only *after* a threshold level of materiality and intent has been proven by clear and convincing evidence.

B. Neither Boneau's Alleged "Suture Stent" Nor Stertzer's Alleged Tradition of Implanting Stents "Crown-to-Crown" Is Prior Art to the Lau Patents

Few principles are as deeply engrained in the patent law as the rule requiring corroboration of oral testimony relating to the alleged existence of prior art. *See generally Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 740-44 (Fed. Cir. 2002) (explaining the origins of the rule). Over a hundred years ago, the Supreme Court recognized the importance of this rule in the famous "Barbed Wire" case:

> The very fact . . . that almost every important patent, from the cotton gin of Whitney to the one under consideration, has been attacked by the testimony of witnesses who imagined they had made similar discoveries long before the patentee had claimed to have invented his device, has tended to throw a certain amount of discredit upon all that class of evidence, and to demand that it be subjected to the closest scrutiny.

The Barbed Wire Patent, 143 U.S. 275, 284-85 (1892).

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[13] Under Rule 56, "the moving party essentially bears two burdens: First, there is the burden of production, of making a prima facie showing that it is entitled to summary judgment. . . . Second, there is the burden of persuasion. This burden is a stringent one which always remains with the moving party." *Prudential Ins. Co. of Am. v. U.S. Gypsum Co.*, 828 F. Supp. 287, 292 (D.N.J. 1993).

As a result of these concerns, it is settled law that "corroboration is required of any witness whose testimony alone is asserted to invalidate a patent." *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1217 (Fed. Cir. 2002) (quoting *Finnigan Corp. v. Int'l Trade Commn.*, 180 F.3d 1354, 1369 (Fed. Cir. 1999)); *accord Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1369 (Fed. Cir. 1998). The corroboration requirement is not limited to "interested" parties but applies to *any* witness who provides oral testimony concerning alleged prior art. *Finnigan*, 180 F.3d at 1369.

The Federal Circuit has held that corroboration preferably comes from contemporaneous, physical records. *See Sandt Tech., Ltd. v. Resco Metal and Plastics Corp.*, 264 F.3d 1344, 1350-51 (Fed. Cir. 2001). As the Court has noted, "[i]t is rare indeed that some physical record (e.g., a written document such as notes, letters, invoices, notebooks, or a sketch or drawing or photograph showing the device, a model, or some other contemporaneous record) does not exist." *Woodland*, 148 F.3d at 1373.

In this case, there is not *one shred* of corroborating evidence—written or otherwise—for Boneau's alleged "suture stent." (D.I. 671 at 152.) Indeed, not even his own former partner, Dr. Stertzer, was apparently willing to corroborate Boneau's "suture stent" story. Therefore, as this Court previously ruled (D.I. 586), the alleged "suture stent" is not prior art. *See Woodlawn*, 148 F.3d at 1373. Nor is it material to the Lau claims. *See Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 940 (Fed. Cir. 1990) ("Since the Viatron 21 device was not prior art, it was not material to patentability.").

Similarly, there is no corroborating evidence for Dr. Stertzer's alleged "tradition" of implanting Boneau stents crown-to-crown in the late 1980's. (D.I. 671 at 85, 158-59.) The undated angiograms produced at trial are not corroborating evidence because Stertzer, himself, could not say when they were made. (*Id.* at 85.) Moreover, Dr. Stertzer's own contemporaneous writings (AX-62), as well as the photograph allegedly shown to ACS in 1990 (DTX-227), indicate that crown-to-crown placement was *not* considered a necessary or important feature of the Boneau technology in 1989-90. Likewise, the fact that Boneau did not discuss the crown-to-crown feature in his patent application (despite the best-mode requirement of 35 U.S.C. § 112) strongly suggests there was no crown-to-crown "tradition" at that time.

In addition to the foregoing, there is no corroborating evidence that Boneau ever *told* ACS about the alleged "suture stent" and "crown-to-crown" concepts (D I 670 at 85, 153) Even if he had, though, that would not have created a duty to submit such uncorroborated and undocumented information to the PTO For instance, in *Life Technologies, Inc. v. Clontech Labs*, 224 F.3d 1320 (Fed Cir. 2000), the patentees were accused of committing inequitable conduct by failing to disclose their knowledge that another party, Dr. Goff, claimed to have invented the same subject matter and presented the results at a conference Dr Goff told this information to the inventors during a telephone conversation The Federal Circuit held that the failure to disclose that information to the PTO was *not* inequitable conduct because:

> At most, the inventors could have disclosed to the PTO that a rival researcher claimed to have reduced RNase H activity in cloned RT and had presented his results at a conference, which neither of the inventors attended . . . [T]his information lacks the specificity and definiteness to support a patentability rejection under 35 U S C § 102(g).

224 F.3d at 1327. *See also Hebert v. Lisle Corp.*, 99 F.3d 1109, 1115-16 (Fed. Cir. 1996) (holding that a patentee had no duty to submit a series of letters informing him that his invention was not novel and, in fact, had already been disclosed by twelve previous inventors); *Hartness Int'l, Inc. v. Simplimatic Engineering Co.*, 819 F.2d 1110, 1107 (Fed Cir 1987) (finding no inequitable conduct where the patentee of a bottling device failed to inform the PTO "that he had 'heard of' [a prior art device] from other bottlers.")

Finally, even assuming the alleged "suture stent" and "crown-to-crown" concepts were prior art (which they are not), they are clearly cumulative to other references that were submitted during the Lau prosecution. As just one example, Gianturco '706 discloses both "crown-to-crown" orientation and Boneau's alleged "suture stent" concept (DTX-1000-53.)

C. The Boneau Patent Application Is Not Material to the Lau Claims

As explained above, the only portion of the so-called "Boneau prior art" that is *actually* prior art is the Boneau patent application Specifically, that application became § 102(e) prior art when the

Boneau '331 patent issued on March 8, 1994 [14] ACS submitted the Boneau '331 patent in three of the four patents-in-suit, but not in the '154 patent Thus, the relevant inquiry here is whether the Boneau application is material to the claims of the '154 patent [15] As explained below, it is not.

1. The Boneau Application Teaches Away from Lau's Invention

Since Medtronic concedes Boneau is not an anticipation reference, the only question that remains is whether it is material as an obviousness reference. The evidence overwhelmingly shows it is not because it *teaches away* from Lau's claimed invention.

As a general rule, "references that teach away cannot serve to create a prima facie case of obviousness." *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed. Cir. 2001). Accordingly, a reference that teaches away from the claimed invention cannot be material. As this Court explained in *Rhenalu*:

> The court concludes that Pechiney has not carried its burden of proving by clear and convincing evidence that the applicants intended to deceive the PTO concerning a material fact during the prosecution of the '639 patent. The 417 Process, including a reset step and solution heat treatment step designed for plate products, *teaches away* from the '639 patent. *Under either standard of materiality*, the court finds that the 417 Process *cannot be considered material because it contains features that contradict the claimed invention*.

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[14] Under § 102(e), another inventor's earlier-filed application is treated as prior art as of its filing date, but *only when* (and if) "a patent [is] granted" on that application (or the application is published under § 122(b), which did not exist in 1991). *See* 35 U.S.C. §§ 102(e)(1) & (2) If an earlier-filed application is abandoned or otherwise does not issue, it is *not* considered prior art. *See In re Lund*, 376 F.2d 982, 991 (CCPA 1967) Thus, the Boneau application did not become prior art until it issued as a patent in 1994, at which point it became retroactively effective as of its filing date.

[15] Medtronic's assertion that the '167, '168, and '133 patents are also unenforceable rests solely on the incorrect premise that the alleged "crown-to-crown" and "suture-stent" concepts are prior art to those patents. (D.I. 683 at 28-29.) With respect to the Boneau application itself (which was cited during prosecution of each of those patents), Medtronic does not state a claim that those patents are "tainted" with inequitable conduct Nor has it established an "immediate and necessary relationship" between those patents and the alleged withholding of Boneau in the '154 patent, as would be required to prove taint. *See Arthrocare Corp. v. Smith & Nephew, Inc.*, 310 F. Supp.2d 638, 679 (D. Del. 2004) (holding that "mere relatedness of subject matter is insufficient to establish [the] immediate and necessary relationship" required to establish infectious unenforceability); *rev'd on other grounds*, 2005 U.S. App. LEXIS 8108 (Fed. Cir. May 10, 2005) Thus, based on Medtronic's opening brief, the issue of "taint" is not before the Court.

224 F. Supp.2d at 806-07 (emphasis added); *see also Halliburton*, 925 F.2d at 1441 ("In making [a materiality] determination, the trial court must consider portions of prior art references which *teach away* from the claimed invention.") (emphasis added)

Here, there is overwhelming proof that Boneau teaches away from the Lau claims because it stresses the importance of using *functional stents* that are *unconnected*, rather than connected rings as claimed in Lau. (D.I. 671 at 565.) Indeed, this Court has previously ruled—based on Boneau's written description—that "each [Boneau] stent must be a functional stent." (D.I. 541 at 3, n.5.) In contrast, all of the Lau claims require "cylindrical elements" that are "*not* in and of themselves stents." (D.I. 542 at 3, emphasis added.) Likewise, it is undisputed that Boneau shows only *unconnected* stents (D.I. 636 at 1419), whereas all of the Lau claims require cylindrical elements that are connected together to form a single stent. Thus, as in *Rhenalu*, Boneau clearly "contradict[s] the claimed invention" and, accordingly, is not material. 225 F. Supp.2d at 807.

The Lau prosecution history—an independent and objective record created by the PTO—likewise confirms that Boneau is not material to the Lau claims. In particular, the PTO never issued a *single rejection* based on Boneau in any of the three patents-in-suit in which Boneau was cited. The PTO instead issued rejections based on numerous other references that it apparently found more material than Boneau. (*Id.* at LJA 1904, 1999, 2087, 2390.) Indeed, at least fifteen Lau patents have issued since Boneau was first cited, without a *single rejection* over Boneau. (D.I. 671 at 360-62.)

The fact that the PTO allowed the claims of the '167, '168, and '133 patents—even after Boneau was submitted and specifically called to the Examiner's attention—strongly indicates that Boneau is not material. As the Federal Circuit has held, "the result of a PTO proceeding that assesses patentability in light of information not originally disclosed can be of *strong probative value* in determining whether the nondisclosed information would have been material." *J.P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc.*, 747 F.2d 1553, 1562 (Fed. Cir. 1984) (emphasis added); *see also Life Techs.*, 224 F.3d at 1327 (holding that the PTO's conclusion that previously undisclosed information had "no bearing on the patents issued or the instant application" was "highly probative of its immateriality")

Consistent with the PTO's actions, the jury in this case found that Boneau '331 does not invalidate any of the asserted Lau claims, even when combined with other references such as Wolff '404 and Schatz '984. (D.I. 629.) The jury reached that verdict after hearing Medtronic's *best evidence* as to why Boneau should be considered a material reference that invalidates the Lau claims.

In contrast to the mountain of evidence showing that Boneau is *not* material, Medtronic offers only the testimony of its two experts, Dr. Wagoner and Professor Saigal. Those gentlemen, however, are not stent experts. (D.I. 636 at 1382-85; D.I. 670 at 175-77; D.I. 671 at 351.) Neither of them has ever implanted a stent, much less designed a stent. (*Id.*) Indeed, far from being experts in the field, they do not even satisfy the minimum requirements of a person of *ordinary* skill in the art:

> Q. The fact is, sir, you don't satisfy the definition of a person of ordinary skill in this art, do you?
> A. I'm not, right

(D.I. 670 at 177, testimony of Dr. Wagoner.)

> Q. And with respect to stents, we agreed you're not a person of skill in the art?
> A. No, I'm not.

(D.I. 671 at 351, testimony of Professor Saigal.) Thus, the opinions of Dr. Wagoner and Professor Saigal can hardly be considered compelling on the question of what Boneau teaches to *persons skilled in the art*.

Lacking an expert skilled in the stent art, Medtronic instead tries to bootstrap the testimony of Mr. Khosravi. Specifically, Medtronic focuses on Khosravi's remark that one could *theoretically* convert the Boneau design into the Lau design by making the Boneau stents "short enough" and cutting multiples out of a single tube such that they are all connected together. (D.I. 683 at 2-3.) Yet, misleadingly, Medtronic omits Khosravi's conclusion, namely that *without* those major theoretical changes, the Boneau design is very different from Lau's:

> Q. [D]o you see the two designs being at all similar?
> A. No.

(D.I. 670 at 289, testimony of Mr. Khosravi.)

Finally, as a last-ditch "materiality" argument, Medtronic asserts that, because Mr. Nagy reportedly called the Boneau patent "relevant" during an interview with the Examiner, that amounts to an admission of *materiality*. (D.I. 683 at 32.) "Relevant," however, does not mean "material."[16] Indeed, contrary to Medtronic's assertion, Mr. Nagy expressly submitted the Boneau reference "[p]ursuant to 37 C.F.R. § 1.97" (LJA 1800), which states:

> The filing of an information disclosure statement *shall not* be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).

37 C.F.R. § 1.97(h). Thus, Mr. Nagy did not admit materiality as Medtronic contends.

2. The Boneau Application Is Cumulative to References That Were Considered by the PTO

"If the withheld information is merely cumulative in light of other references considered by the examiner, the information is not material." *Tap Pharmaceutical Prods., Inc. v. Owl Pharmaceuticals, L.L.C.*, 2005 WL 1981449 (Fed. Cir. Aug. 18, 2005). Here, there is little doubt that Boneau is cumulative to other references submitted during the Lau prosecution. For example, Lee '917 discloses *each and every* feature that Medtronic claims is relevant in Boneau, i.e., a "single-ring, balloon-expandable, plastically deformable, sinusoidal or zigzag shaped stent, capable of being crimped onto a balloon catheter" (D.I. 683 at 22-23), measuring as little as 1 mm in length (*id.* at 31, n.15), implanted in multiples (*id.* at 22-23), and having "L<D in all three stent states" (*id.* at 26).[17] Moreover, when that list of features is trimmed to what is *actually* relevant to the '154 claims, Boneau is also cumulative to Palmaz '417.

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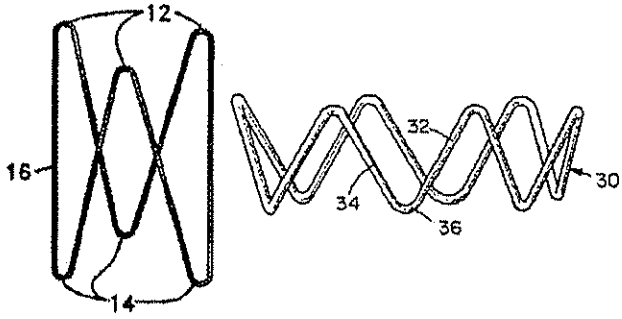
[16] "Material" has a special legal meaning in the patent law, whereas "relevant" does not. Under the Federal Rules of Evidence, "relevant" is understood to connote a minimal or mere threshold relationship between two things. *See, e.g., In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 784 (3d Cir. 1994) (noting "the low threshold of relevancy of Rule 401"); *accord Oddzon Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1406-07 (Fed. Cir. 1997) (noting the "low threshold for relevancy"). "Materiality," in contrast, entails a much more demanding standard under 37 C.F.R. § 1.56.

[17] ACS does not agree that all of these features are relevant to the Lau claims. For instance, the "capab[ility] of being crimped onto a balloon catheter" and "L<D in *all three* stent states" are not required by any of the '154 claims. Yet, assuming *arguendo* that those features are relevant to the Lau claims, they are nevertheless disclosed in Lee '917.

a. Lee '917

Lee '917 was submitted to the PTO at the very beginning of the Lau prosecution. (AX-2586 at LJA 136) It discloses a plurality of "ring-like scaffold members" (DTX-1000-79, col. 2:36-37) that are nearly identical in every relevant respect to the Boneau stent. Indeed, as the table below shows, Lee '917 discloses *every feature* of Boneau that Medtronic touts as being relevant to the Lau claims, even those that are clearly not relevant (e g , the ability to be "crimped") and those that are not actually disclosed in Boneau (e.g., 1 mm rings) In other words, this table proves that Boneau is cumulative to Lee '917, even under the *most favorable* view of Boneau and Lau that Medtronic can muster.



Boneau '331 (left) and Lee '917 (right) both disclose stainless steel, balloon-expandable, zigzag structures for use in coronary arteries.

Alleged Relevant Features of Boneau	**Lee '917 (DTX-1000-79)**
single-ring, balloon-expandable, plastically deformable, sinusoidal or zigzag shaped stent,	Fig. 5 clearly shows a sinusoidal or zig-zag shaped, one-piece ring. The rings are mounted on a balloon (col. 5:62-63) and are "deformed beyond their elastic limit when the graft is expanded" (col. 2:51-53).
capable of being crimped onto a balloon catheter [NOTE: *not relevant to the Lau '154 claims*]	Lee discloses that the plastically-deformable scaffold members are "mounted" on a balloon. (col. 5:62.) Dr. Segal testified that the rings of Lee are "clearly crimpable" (D I 671 at 584-85.) "That was commonly the way you do this with balloon expandable stents" (*Id.*)
measuring as little as 1 mm in length [NOTE: *not disclosed in Boneau*]	Dr. Segal testified that, based on the description in Lee, the rings shown in Fig 1 are "between 1 millimeter and 2 millimeters in length" (*Id.* at 581)
implanted in multiples,	Figs. 1 and 2 depict multiple rings being delivered on a single balloon.
having L<D in all three states [NOTE: *not disclosed in Boneau, and the Lau '154 claims require L<D only in one state*]	Figs. 1 and 2 of Lee clearly show that each ring has L<D in both the delivery and expanded state. Dr. Segal further confirmed that they have a "length less than diameter in all states" (*Id.* at 583)

Though Medtronic boldly asserts that Lee '917 "is far less material to Lau than Boneau" (D.I. 683 at 30), its support for that assertion is decidedly lacking. For instance, Medtronic first criticizes Lee '917 for not disclosing L<D in any state. (D.I. 683 at 30.) That puzzling assertion—which simply ignores Figs. 1, 2, and 5 of Lee—is apparently based on Professor Saigal's opinion that L<D must be measured with respect to the *entire stent* of Lee, not just the scaffold members (which he likened to "straps" around a "suitcase"). (D.I. 671 at 367-68, 374-75.) Yet the Lau claims do not require the entire *stent* to have L<D, as Professor Saigal's twisted logic assumes; they require *cylindrical elements* to have L<D. It is undisputed that the scaffold members of Lee '917 satisfy that requirement. (D.I. 671 at 367-69.)

Medtronic next criticizes Lee '917 for not disclosing "out of phase." Yet the Boneau application *also* does not disclose "out of phase." (D.I. 670 at 144.) Therefore, the concept of "out of phase" simply has no relevance to the question of whether the Boneau application is cumulative to Lee '917. Indeed, Medtronic's constant attempt to *blend* the Boneau application with other (non-prior-art) information, such as Stertzer's alleged "crown to crown" tradition, is a tacit admission that the Boneau application—by itself—is cumulative to Lee '917.

The rest of Medtronic's alleged distinctions are likewise illusory. For instance, Professor Saigal opined (for the first time on *cross examination*) that Lee '917 is distinguishable because it is not "crimpable." (D.I. 671 at 364.) That alleged distinction, however, is both technically wrong (*see id.* at 584-85) and legally irrelevant since none of the Lau '154 claims *require* the ability to be crimped (*id.* at 369, 586-89). Indeed, Medtronic now appears to have dropped that argument. In its place, Medtronic contends that Lee is distinguishable because it discloses "rings that are spaced apart by 3 to 4 millimeters," allegedly too far apart to cover a lesion. (D.I. 683 at 30.) Because the Boneau application discloses *nothing* about the spacing between stents, however, that feature cannot render Boneau non-cumulative. Moreover, Lee '917 does not *require* spacing of 3-4 mm as Medtronic contends. (*See* DTX-1000-79, col. 5:32-32 ("The rings 30 *can* be spaced apart by between 3 and 4 mm *if desired*.").)

Finally, as a would-be "silver bullet," Medtronic argues that Lee '917 is not even prior art because, allegedly, "Mr. Lau could have effectively 'sworn behind'" it during prosecution. (D.I. 683 at 30.) Yet, tellingly, Medtronic cites no authority for that untenable proposition.

The Lee '917 patent is prior art *on its face* under 35 U.S.C. § 102(e) because it was filed April 27, 1990, eighteen months before the Lau application was filed. (DTX-1000-79.) Indeed, Lee is prior art under the very same provision that renders Boneau prior art to the Lau patents. Nevertheless, Medtronic speculates that Mr. Lau could have "sworn behind" Lee '917 during prosecution by filing a declaration under 37 C.F.R. § 1.131.[18] The fact is, however, Mr. Lau *did not do so*.

Lee '917 was available to the PTO *as prior art*, and the Examiner could have issued a rejection over it at any time. Medtronic's argument that Mr. Lau *might* have sworn behind Lee '917 (had the PTO issued a rejection) is purely speculative.[19] Moreover, it completely misses the point. Namely, contrary to Medtronic's assertion that ACS intentionally withheld Boneau because of its alleged materiality, ACS in fact submitted Lee '917—which is cumulative to Boneau in every relevant respect—*and the PTO never issued a rejection over it*.

b. Palmaz '417

During the liability trial in February, Medtronic argued vehemently to the Court that Palmaz '417 (a.k.a. "Spiral Palmaz") *anticipates* the Lau '154 claims and thus, as a matter of law, discloses "each element of each asserted claim." (D.I. 627 at 1.) In contrast, Medtronic asserted Boneau only as an *obviousness* reference. As Professor Saigal acknowledged (D.I. 671 at 355-56), a reference that anticipates is "closer" to the claimed invention than a mere obviousness reference. *See Connell v. Sears,*

[18] To swear behind a prior art reference, the inventor must file an oath or declaration, setting forth facts that "establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to filing of the application." 37 C.F.R. § 1.131(b).

[19] The problem with such speculation is that there is no end to it. For instance, Mr. Lau might have opted *not* to file a Rule 131 affidavit for any number of reasons, including that Lee '917 is cumulative to other references with earlier filing dates. Mr. Lau *might* have opted to address the merits of a Lee '917 rejection rather than trying to swear behind it. We simply do not know what Mr. Lau *might* have done.

Roebuck & Co., 722 F.2d 1542, 1548 (Fed. Cir. 1983) ("anticipation is the epitome of obviousness"). Thus, by asserting Palmaz '417 as the sole anticipation reference, Medtronic admitted that Palmaz '417 is "closer"—and therefore more material—to the Lau '154 claims than the Boneau application. *See CFM Corp. v. Dimplex N.A., Ltd.*, 2005 WL 1432902 (May 11, 2005 N.D. Ill.); *Rolls-Royce Ltd. v. GTE Valeron Corp.*, 800 F.2d 1101, 1107 (Fed. Cir. 1986).

In *CFM*, the accused infringer (CFM) asserted that two different references, the '921 application and the Butterfield patent, anticipated the claimed invention. 2005 WL 1432902 at *2. The Butterfield reference had been submitted to the PTO, but the '921 reference had not. Therefore, CFM attempted to argue that the failure to submit the '921 reference amounted to inequitable conduct. *Id.* But the district court remarked that, "[h]ere CFM is faced with a problem." *Id.* Namely, by arguing that Butterfield—a *cited* reference—anticipated the claimed invention, CFM had essentially conceded that the '921 patent was no more than cumulative to the cited art:

> [T]he '921 application would be material unless it was cumulative to the references that were before the PTO. Here, however, CFM is faced with a problem: Dr. Barudi [CFM's expert] *also* contended that each and every element of the '580 patent was contained in [the] Butterfield patent, including the so-call "flicker element."

Id. (emphasis added). The court concluded that CFM had failed to prove materiality by clear and convincing evidence. *Id.*

A similar situation arose in *Rolls-Royce*, 800 F.2d at 1107, where the defendant asserted two different anticipation references but attempted to argue that one was more material than the other. The Federal Circuit found that argument "implausible" in view of the defendant's assertion that *both* references anticipated the claimed invention. *Id.* ("If that were true, it would be difficult to argue any substantial difference in materiality.")

Here, the situation is even more compelling than in *CFM* and *Rolls-Royce* because Medtronic has asserted the *cited* reference as an anticipation (i.e., saying that Palmaz '417 has all the required elements of the Lau claims) and the *uncited* reference only for obviousness (i.e., acknowledging that Boneau has some, but not all, of the required elements). To escape this *glaring problem* with its case, Medtronic has

devised two tactics, both unavailing. First, it has expanded the so-called "Boneau prior art" to include information beyond the Boneau application itself, such as Stertzer's alleged crown-to-crown "tradition." As explained above, however, that additional information is *not* prior art and, therefore, cannot be used to show non-cumulativeness. Second, Medtronic has flip-flopped on whether Palmaz '417 discloses L<D. Specifically, Medtronic filed a *signed pleading* in February stating that Palmaz '417 discloses "each element" of the '154 claims. (D.I. 627.) Indeed, it made the same argument in its new-trial motion, which is *currently pending* before the Court. (D.I. 653 at 23-26.) Yet Medtronic now says Palmaz '417 is incomplete because it fails to disclose L<D "in all three stent states." (D.I. 683 at 30.) Such unabashed opportunism is simply outrageous, particularly where people's reputations and livelihoods are at stake, as they are here.

D. There Is No Evidence That ACS Intended to Deceive the PTO

"In a case involving an omission of a material reference to the PTO, there must be clear and convincing evidence that the applicant made a *deliberate decision* to withhold a *known* material reference." *Baxter Int'l, Inc.*, 149 F.3d at 1329 (emphasis added). Here, Medtronic has not offered any proof that ACS (1) *knew* the Boneau application was material and (2) *deliberately* withheld it with an intent to deceive the PTO. Absent clear and convincing proof of those *threshold* requirements, there cannot be a finding of inequitable conduct. *Id.* at 1327.

1. There Is No Evidence That Anyone Involved in the Lau Prosecution Knew of the Boneau Application and Subjectively Believed It to Be Material to the Lau Claims

Messrs. Lau, Khosravi, and Orth all testified that they believed Boneau's stent to be a very different design from Lau's. (D.I. 670 at 289; D.I. 671 at 394-95, 476-83.) That testimony is corroborated by the 1990 feasibility study, which literally ranked the two designs on opposite ends of the spectrum. (AX-268.) Likewise, the Boneau stents that were shown to ACS in 1990 were all stand-alone stents, measuring between 4 and 7 mm, and not connected together. (D.I. 671 at 398, 479; D.I. 670 at 94-95.) Those features are *inconsistent* with Lau's claimed invention.

There is no evidence that Mr. Lau—or *anyone* at ACS who was substantively involved in the Lau prosecution—had knowledge of the Boneau patent application.[20] As for ACS's outside counsel, Mr. Lynch spent about seven hours on a project involving the Boneau application in early 1990. Yet there is no evidence that he even *recalled* the Boneau application when he filed the initial Lau application (some eighteen months later), let alone believed it to be material to the Lau claims. *See Nordberg*, 82 F.3d at 397 ("The fact that information was known years ago does not mean that it was recognized that the information is material to the present application.")

Medtronic criticizes ACS for not calling Mr. Nagy to testify and suggests (absurdly) that an intent to deceive can be drawn from that fact. (D.I. 683 at 39.) Yet Medtronic—*who bears the burden of proof on this issue*—never bothered to depose Mr. Nagy in the seven years this case has been proceeding. Indeed, just one month before trial, Medtronic continued to name *Mr. Lynch*—not Mr. Nagy—as the central player in its inequitable conduct allegations. (D.I. 664 at Ex. 12.) ACS brought Mr. Lynch to trial to rebut those false accusations, but now Medtronic blames ACS for not calling *more* people to testify, e.g., Mr. Nagy, Ms. McDermott, Mr. Barclay, Dr. Schneiderman, etc.

In the six hours allotted to it at trial, ACS presented testimony from Mr. Lau (the inventor), Mr. Lynch (the *only* prosecuting attorney accused by name of wrongdoing), Mr. Orth (the former manager of the Stent Business Unit), and Dr. Segal (ACS's technical expert). That hardly compares to the situation in *A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392 (Fed. Cir. 1986), where the patentee failed to call either the inventor or the prosecuting attorney. Thus, there is absolutely no basis for drawing an "adverse inference" against ACS, as Medtronic urges the Court to do.

[20] 37 C.F.R. § 1.56 applies only to "*individuals* associated with the filing or prosecution of a patent application." It does not apply to organizations generally, nor does it apply to individuals who had no involvement in the prosecution. *See Nordberg, Inc. v. Telsmith, Inc.*, 82 F.3d 394, 397 (Fed. Cir. 1996).

2. There Is No Evidence That ACS Withheld the Boneau Application With an Intent to Deceive the PTO

Medtronic all but concedes it does not have any direct evidence of deceptive intent but, instead, is asking for an inference to satisfy its burden on that issue. First, Medtronic argues that it is entitled to such an inference because it has made an "overwhelming showing of materiality plus [ACS's] knowledge of that materiality." (D.I. 683 at 33.) As explained above, however, Medtronic has made no such showing.

Medtronic next asks for an inference based on its theory of a vast conspiracy at ACS—involving numerous executives, engineers, and attorneys—to cheat Mr. Boneau and simultaneously conceal his patent application from the PTO. Since there is no *evidence* of such a conspiracy, Medtronic instead asks the Court to draw yet another inference, namely that Mr. Lynch's report of January 17, 1990 *must* contain information adverse to ACS because ACS has asserted the attorney-client privilege. (D.I. 683 at 37.) Yet that argument is plainly improper. As the Federal Circuit recently confirmed, "no adverse inference shall arise from invocation of the attorney-client and/or work product privilege." *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1344-45 (Fed. Cir. 2004); *see also In re Tudor Associates, Ltd., II*, 20 F.3d 115, 120 (4th Cir. 1994) ("A negative inference should not be drawn from the proper invocation of the attorney-client privilege.")

To cure Medtronic's improper argument, ACS is willing to submit Mr. Lynch's January 17, 1990 report to the Court for *in camera* inspection. Yet Medtronic refuses to agree that ACS may do so without waiving the attorney-client privilege. (*See* Ex. F hereto.) Thus, it is Medtronic—not ACS—who "has decided that, strategically, it is better to conceal this information from the Court than to disclose it." (*See* D.I. 683 at 37.)

Medtronic next offers a grab bag of pseudo-"inference" arguments, none of which has any legal or factual merit. *See FMC Corp. v. Manitowoc, Co.*,, 835 F.2d 1411, 1417 (Fed. Cir. 1987) ("An inference often must be drawn from established facts . . ., but drawing an inference on an inference on an inference is not the role of the fact finder."). For instance, Medtronic contends that deceptive intent can be inferred from the fact that ACS cited an "ear wick" patent (Haerr '719) to the PTO, allegedly as an

attempt to "bury" more relevant art (D.I. 683 at 34.) Yet Mr. Boneau cited the *very same* "ear wick" patent in *his* patent application (D.I. 422 at BJA 24-39), thus making Medtronic's "ear wick" argument not only meritless as a legal matter, but also quite hypocritical. Likewise, Medtronic argues that deceptive intent can be inferred from the fact that ACS cited Boneau four months before filing suit against AVE, allegedly as an effort to "minimize the scrutiny the art would receive." (D.I. 683 at 35.) Medtronic, however, has shown no link between those two events and has produced not one iota of proof to support such an inference. Medtronic next asserts that ACS's "corporate amnesia" shows an intent to deceive the PTO. (D.I. 683 at 37.) Yet the inability of ACS's fact witnesses to remember events as *Mr. Boneau* claims they occurred hardly constitutes "corporate amnesia" (particularly since none of those witnesses even works for ACS anymore). Indeed, Dr. Stertzer—Boneau's former partner—was also unable to corroborate most of Boneau's testimony regarding the events of fifteen years ago.

Finally, as a last desperate tactic (and an acknowledgement that it cannot prove deceptive intent), Medtronic invites the Court to overturn *centuries* of common law by placing the burden on ACS in this case to *disprove* deceptive intent. (D.I. 683 at 35.) As explained above, however, that view of the law is completely backwards. Medtronic bears the burden of proving deceptive intent by clear and convincing evidence. *Hebert*, 99 F.3d at 1116. It cannot "shift" that heavy burden to ACS simply by concocting a fictitious conspiracy theory.

Moreover, contrary to Medtronic's assertion that ACS failed "to offer any evidence of good faith," the record shows otherwise. To begin with, ACS submitted the Boneau reference in *three out of the four patents-in-suit*, bringing it to the Examiner's attention both in an interview and in a supplemental IDS. The Federal Circuit has held that such behavior "is not consistent with an intent to deceive." *Kimberly-Clark Corp. v. Proctor & Gamble Dist. Co.*, 973 F.2d 911, 918 (Fed. Cir. 1992). Indeed, if ACS intended to *conceal* Boneau from the PTO, as Medtronic contends, submitting it to the Examiner and calling attention to it would seem to be a very odd tactic.

ACS also submitted over *one hundred* prior-art references to the PTO, including many that the PTO apparently found more material than Boneau. For instance, ACS submitted Lee '917, which

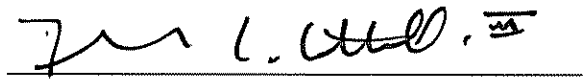
discloses *each and every* feature that Medtronic claims is material about Boneau. ACS also submitted Palmaz '417, the *only* anticipation reference asserted in this case. This clearly rebuts any inference that ACS was somehow trying to "conceal" the best prior art from the Examiner.

Finally, contrary to Medtronic's assertion that ACS presented no evidence of good faith, ACS called Messrs. Lau, Lynch, and Orth to *personally* answer Medtronic's allegation that they (and others) conspired to cheat Mr. Boneau and defraud the PTO. They flatly denied doing so. Moreover, their testimony—unlike Mr. Boneau's—was corroborated, logical, and completely consistent with the other evidence. Medtronic's *only* response to this compelling evidence of good faith is that it should be excluded as inadmissible character and habit evidence. (D.I. 683 at 36.) Yet it was *Medtronic* who put these individuals' character and habit at issue by accusing them of wrongdoing. Medtronic's argument that their exculpatory testimony should now be excluded is thus legally improper. *See* Fed. R. Evid. 404(a)(1) & 406.

IV. CONCLUSION

Because Medtronic's reckless allegations of inequitable conduct are entirely baseless—akin to what the Federal Circuit has condemned as an "absolute plague" on the patent system, *Burlington Industries, Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988)—this Court should deny Medtronic's request in full and enter an Order finding that the Lau '154, '167, '168, and '133 patents are not unenforceable due to inequitable conduct.

Dated: September 19, 2005



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CERTIFICATE OF SERVICE

I hereby certify that on September 19, 2005, I caused to be served by hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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